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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,884	07/25/2003	Hans-Joerg Buehring	WWELL73.004AUS	3837

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EXAMINER	
GAMETT, DANIEL C	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,884	BUEHRING ET AL.	
	Examiner	Art Unit	
	Daniel C. Gamett, PhD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *11-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 18-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/05/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Claims 1-10 and 18-27 in the reply filed on 04/14/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 11-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/14/2006. If a product claim is subsequently found allowable, withdrawn process claims of Group II and Group III that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04 and fully examined for patentability.

3. Claims 1-10 and 18-27 are under consideration.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-10 and 18-27 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention employs novel biological materials, specifically the hybridoma cell lines CUB1, CUB2, CUB3, and CUB4. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification

or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials. It is noted that Applicants have deposited the biological materials on under the terms of the Budapest Treaty. Applicants' referral to said deposit on pages 6 and10 of the specification and in claims 11-5, 11, and 12, is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. Applicant is referred to MPEP 2404.01, which states in pertinent part:

> The mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990)

6. The filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 6, 18, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "an antibody which is produced by the hybridoma cell lines CUB1, CUB2, CUB3, and CUB4" is ambiguous. Each hybridoma produces a different antibody; "an antibody" (singular) cannot be simultaneously produced by all four hybridomas. Therefore, Applicants may intend to recite "lines CUB1, CUB2, CUB3, *or* CUB4". Alternatively, Applicant may intend that the generic antibody or fragment being claimed binds an antigen that has all of the epitopes bound by *each of* lines CUB1, CUB2, CUB3, and CUB4. Certain claims dependent from claim 1 (e.g. 2-5) correct the ambiguity by reciting a specific hybridoma, claims 6, 18, and 23 do not.

9. In view of the potential rejoinder of non-elected process claims, Applicants are advised that each of the non-elected claims recites "an antibody which is produced by the hybridoma cell lines CUB1, CUB2, CUB3, and CUB4", either explicitly or by dependence from claim 1.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-10 and 18-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Conze *et al.*, Ann N Y Acad Sci. 2003 May;996:222-6 (Citation 7, IDS filed 04/05/2004). The Conze *et al.* publication teaches (throughout) each of the hybridomas and antibodies of the present disclosure. The authorship of the Conze *et al.*, publication includes individuals who are not listed as inventors on the instant application, indicating that the claimed invention was known and used by others. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

12. Claims 1,6,18, and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Hooper *et al.*, Oncogene, 2003 Mar 27;22(12):1783-94. The claims are drawn to a monoclonal antibody, or fragments thereof, wherein the antibody, or a fragment thereof, binds to an antigen which is the same as that bound by an antibody which is produced by the hybridoma cell lines CUB1, CUB2, CUB3 and CUB4 (claim 1) and the hybridoma cell line that produces said antibody (claim 6). Dependent claims 18 and 23 recite a pharmaceutical composition and a kit, respectively, but the only recited component is the antibody of claim 1. The specification teaches that the antibodies produced by hybridoma cell lines CUB1, CUB2, CUB3, and CUB4 bind to a cell surface protein designated CDCP1. Hooper *et al.* developed a monoclonal antibody, mAB 41-2, that binds to CDCP1 as demonstrated by immunofluorescence (figure 4), immunoprecitation, and western blotting (figure 5). Thus, mAB 41-2 is a monoclonal antibody that binds to the same antigen as the antibodies recited in claim 1 and therefore, 1,6,18, and 23

are anticipated. The intended use recited in instant claim 1 does not distinguish the antibodies of the instant claims from the antibody in the prior art. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

13. Claims 1,6,18, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6245898, June 12, 2002. Patent 6245898 teaches (throughout; see Abstract and claim 1) mAB 41-2, the same as described by Hooper *et al.*, (see above). Therefore, Patent 6245898 anticipates claims 1,6,18, and 23 for the same reasons as given above with respect to Hooper *et al.*

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D.,whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG
Art Unit 1647
7 December 2006

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